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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,376

05/12/2006

Jerome S. Brody

AFMX-077-101

8226

75436

7590

02/21/2008

MORSE, BARNES-BROWN & PENDLETON, P.C.

ATTN: PATENT MANAGER

RESERVOIR PLACE

1601 TRAPELO ROAD, SUITE 205

WALTHAM, MA 02451

EXAMINER

SALMON, KATHERINE D

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

02/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/579,376

Applicant(s)

BRODY ET AL.

Examiner

KATHERINE SALMON

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 13, 14, 17, 20-24, 26, 32-38, 45, 46 and 50-53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-5, 7, 13, 14, 17, 20-24, 26, 32-38, 45-46, and 50-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

1. The claims submitted 5/12/2007 had duplicate #25 in the claim set. A marked up copy of the claims correcting the numbering has been added to the prosecution history to correct the duplicate numbering (2/14/2008).
2. Based on the corrected claim numbering, Claims 6, 8-12, 15-16, 18-19, 25, 27-31, 39-44, and 47-49 have been cancelled. Claims 1-5, 7, 13-14, 17, 20-24, 26, 32-38, 45-46, and 50-53 are pending.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 7, 13-14, drawn to a kit comprising a scraping instrument, a storage vessel, and stabilizing solution to collect RNA.

Group II, claim(s) 17, 20-23, and 26, drawn to a method to isolate nucleic acid from the mouth epithelial cells.

Group III, claim(s) 32-38, 45-46, 50-53, drawn to a method comprising taking a biological sample and analyzing whether there is a genetic alteration in at least one gene of the mouth transcriptome genes.

4. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

As discussed below, a restriction requirement is being made such that applicant is required to further elect for **Groups III, a specific gene or a specific combination of genes from the genes listed.**

The claims are drawn to "at least one" from the group comprising the least of genes. Therefore each different combination of a specific gene or specific combinations of genes are separate inventive concepts.

For example, each of the following are combinations which are represented in each of the Groups presented above and each represents a different inventive concept:

- A. the combination of ABCC1 and ABHD2
- B. the combination of TXNRD1 and UBE2J1
- C. the combination of LYPLA1.

These combinations of genes do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the description fails to disclose that all of the genes in each of the combinations share a common property or activity. While each combination of genes might serve to detect its own respective full length DNA, due to the lack of sequence homology between each gene, one gene cannot be used to amplify the same region of DNA as another.

In the preceding example, the region that is amplified in Combination A is distinct from the regions amplified in Combinations B and C, and vice versa. Therefore each combination of genes represents a different inventive concept

Moreover, since the polynucleotides are not homologous to each other, they fail

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to share a common structure, i.e., a significant structural element. The sugar-phosphate backbone cannot be considered a significant structural element, since all nucleic acid molecules share it. Therefore, the genes do not share any significant structural element and cannot be considered as having the same or corresponding technical feature.

The mere fact that genes are derived from the same source (human genome) is not sufficient to meet the criteria for unity of invention. The polynucleotides fail to share a common property or activity and fail to share a common structure. Since neither of these two requirements is met, the group of polynucleotide molecules claimed does not meet the requirement of unity of invention.

Therefore applicant is required to elect a specific **gene or a SPECIFIC combination of genes**.

4. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature, which is shared by Groups I-III, is a kit comprising a scraping instrument, a storage vessel and a stabilizing solution. Groups I-III do not share a special technical feature over the art because Freeman et al. (Behavior Genetics January 2003 Vol. 33 p. 67) teaches a scraping instrument in the form of cotton swabs which are used to scrape the inside of the mouth to remove cells

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(p. 68 1st column), a storage vessel in the form of plastic tubes (p. 68 1st column), and stabilizing solution in the form of a collection buffer (p. 68 1st column). Therefore, kit comprising a scraping instrument, a storage vessel and a stabilizing solution fails to make a contribution over the prior art; there is no special technical feature between Groups I-III.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected

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invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine Salmon/
Examiner, Art Unit 1634

/Ram R. Shukla/
Supervisory Patent Examiner, Art Unit 1634